ORIGINAL

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 04-1128V
(To be published)

FILED
DEC 18 2015
OSM
U.S. COURT OF
FEDERAL CLAIMS

DARIUS CANUTO and TERESITA CANUTO, Parents of DAC,	*	
Petitioners,	*	Filed: December 18, 2015
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Vaccine Act Entitlement; Autism; DTP vaccine; DTaP vaccine; Decision without a Hearing.
Respondent.	*	

Darius and Teresita Canuto, Panorama City, CA, pro se petitioners.
Lynn E. Ricciardella, U.S. Department of Justice, Washington, DC, for respondent.

DECISION

HASTINGS, *Special Master*

This is an action in which the Petitioners, Darius and Teresita Canuto, seek an award under the National Vaccine Injury Compensation Program (hereinafter "the Program"[1]), on account of a disorder of their son, DAC, known as an "autism spectrum disorder" ("ASD"), which they believe was caused by his receipt of, *inter alia*, a series of diphtheria, pertussis, and tetanus ("DTP") vaccinations.[2] For the reasons set forth below, I conclude that Petitioners are not entitled to an award.

[1] The applicable statutory provisions defining the Program are found at 42 U.S.C. § 300aa-10 *et seq.* (2012 ed.). Hereinafter, for ease of citation, all "§" references will be to 42 U.S.C. (2012 ed.). At this time, I may also refer to the Act of Congress that created the Program or the "Vaccine Act."

[2] In fact, Petitioners at various times have pointed to a number of DAC's vaccinations as allegedly being causal; however, as described in greater detail below, this Decision focuses primarily on DAC's DTP vaccines, because those are the only vaccinations addressed by *Petitioners' expert* in this case.

I

THE APPLICABLE STATUTORY SCHEME

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury. In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination, and the petitioner is automatically entitled to compensation, unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B).

In other cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). ("Causation-in-fact" is also known as "actual causation.") In such a situation, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination initially caused, or significantly aggravated, the injury in question. *Althen v. HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination initially caused or aggravated the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or aggravation, but must demonstrate that the vaccination was at least a "substantial factor" in causing or aggravating the condition, and was a "but for" cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury;" and the logical sequence must be supported by "reputable medical or scientific explanation, *i.e.*, evidence in the form of scientific studies or expert medical testimony." *Althen*, 418 F.3d at 1278; *Grant v. HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

The *Althen* court also provided additional discussion of the "causation-in-fact" standard, as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a

> showing of proximate temporal relationship between vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from *medical literature* supporting petitioner's causation contention, so long as the petitioner supplies the *medical opinion* of an expert. (*Id.* at 1279-80.) The court also indicated that, in finding causation, a Program fact-finder may rely upon "circumstantial evidence," which the court found to be consistent with the "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." (*Id.* at 1280.)

Since *Althen*, the Federal Circuit has addressed the causation-in-fact standard in several additional rulings, which have affirmed the applicability of the *Althen* test, and afforded further instruction for resolving causation-in-fact issues. In *Capizzano v. HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006), the court cautioned Program fact-finders against narrowly construing the second element of the *Althen* test, confirming that circumstantial evidence and medical opinion, sometimes in the form of notations of treating physicians in the vaccinee's medical records, may in a particular case be sufficient to satisfy that second element of the *Althen* test. Both *Pafford v. HHS*, 451 F.3d 1352, 1355 (Fed. Cir. 2006), and *Walther v. HHS*, 485 F.3d 1146, 1150 (Fed. Cir. 2007), discussed the issue of which party bears the burden of ruling out potential non-vaccine causes. *DeBazan v. HHS*, 539 F.3d 1347 (Fed. Cir. 2008), concerned an issue of what evidence the special master may consider in deciding the initial question of whether the petitioner has met her causation burden. The issue of the temporal relationship between vaccination and the onset of an alleged injury was further discussed in *Locane v. HHS*, 685 F.3d 1375 (Fed. Cir. 2012), and *W.C. v. HHS*, 704 F.3d 1352 (Fed. Cir. 2013). *Moberly v. HHS*, 592 F.3d 1315 (Fed. Cir. 2010), concluded that the "preponderance of the evidence" standard that applies to Vaccine Act cases is the same as the standard used in traditional tort cases, so that *conclusive* proof involving medical literature or epidemiology is *not* needed, but demonstration of causation must be more than "plausible" or "possible." Both *Andreu v. HHS*, 569 F.3d 1367 (Fed. Cir. 2009), and *Porter v. HHS*, 663 F.3d 1242 (Fed. Cir. 2011), considered when a determination concerning an expert's credibility may reasonably affect the outcome of a causation inquiry. *Broekelschen v. HHS*, 618 F.3d 1339 (Fed. Cir. 2010), found that it was appropriate for a special master to determine the reliability of a diagnosis before analyzing the likelihood of vaccine causation. *Lombardi v. HHS*, 656 F.3d 1343 (Fed. Cir. 2011), and *Hibbard v. HHS*, 698 F.3d 1355 (Fed. Cir. 2012), both again explored the importance of assessing the accuracy of the diagnosis that supports a claimant's theory of causation. *Doe 11* v. HHS, 601 F.3d 1349 (Fed. Cir. 2010) and *Deribeaux v. HHS*, 717 F.3d 1363 (Fed. Cir. 2013), both discuss the burden of proof necessary to establish that a "factor unrelated" to a vaccine may have caused the alleged injury.

Another important aspect of the causation-in-fact case law under the Program concerns the factors that a special master should consider in evaluating the reliability of expert testimony and other scientific evidence relating to causation issues. In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the Supreme Court listed certain factors that federal trial courts should utilize in evaluating proposed expert testimony concerning scientific issues. In *Terran v. HHS*, 195 F.3d 1302, 1316 (Fed. Cir. 1999), the Federal Circuit ruled that it is

appropriate for special masters to utilize *Daubert*'s factors as a framework for evaluating the reliability of causation-in-fact theories presented in Program cases.

II

BACKGROUND: THE OMNIBUS AUTISM PROCEEDING ("OAP")

This case is one of more than 5,400 cases filed under the Program in which petitioners alleged that conditions known as "autism" or "autism spectrum disorders" ("ASD")[3] were caused by one or more vaccinations. A special proceeding known as the Omnibus Autism Proceeding ("OAP") was developed to manage these cases within the Office of Special Masters ("OSM"). A detailed history of the controversy regarding vaccines and autism, along with a history of the development of the OAP, was set forth in the six entitlement decisions issued as "test cases" for two theories of causation litigated in the OAP (see cases cited below), and will only be summarized here.

A group called the Petitioners' Steering Committee ("PSC") was formed in 2002 by the many attorneys who represented Vaccine Act petitioners who raised autism-related claims. About 180 attorneys participated in the PSC. Their responsibility was to develop any available evidence indicating that vaccines could contribute to causing autism, and eventually present that evidence in a series of "test cases," exploring the issue of whether vaccines could cause autism, and, if so, in what circumstances. Ultimately, the PSC selected groups of attorneys to present evidence in two different sets of "test cases" during many weeks of trial in 2007 and 2008. In the six test cases, the PSC presented two separate theories concerning the causation of ASDs. The first theory alleged that the *measles* portion of the measles, mumps, rubella ("MMR") vaccine could cause ASDs. That theory was presented in three separate Program test cases during several weeks of trial in 2007. The second theory alleged that the mercury contained in *thimerosal-containing vaccines* could directly affect an infant's brain, thereby substantially contributing to the causation of ASD. That theory was presented in three additional test cases during several weeks of trial in 2008.

Decisions in each of the three test cases pertaining to the PSC's *first* theory rejected the petitioners' causation theories. *Cedillo v. HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).[4] Decisions in each of the three "test cases" pertaining to the PSC's *second* theory also rejected the

[3] "Autism Spectrum Disorder" is a *general* classification, which as of 2010 included five different specific disorders: Autistic Disorder, Childhood Disintegrative Disorder, Asperger's Syndrome, Rett Syndrome, and Pervasive Developmental Disorder Not Otherwise Specified (PDD-NOS). *King v. HHS*, No. 03-584V, 2009 WL 892296 at *5 (Fed. Cl. Spec. Mstr. Feb. 12, 2010). The term "autism" is often utilized to encompass *all* of the types of disorders falling within the autism spectrum. (*Id.*) I recognize that since the OAP test cases, the consensus description of ASDs, contained now in the "DSM-V" as opposed to the prior "DSM-IV," revises the prior subcategories of ASD set forth in the first sentence of this footnote. However, the DSM-V retains the same *general description* of ASDs.

[4] The petitioners in *Snyder* did not appeal the decision of the U.S. Court of Federal Claims.

petitioners' causation theories, and the petitioners in each of those three cases chose not to appeal. *Dwyer v. HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar 12, 2010); *Mead v. HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

The "test case" decisions were comprehensive, analyzing in detail all of the evidence presented on both sides. The three test case decisions concerning the PSC's *first* theory (concerning the MMR vaccine) totaled more than 600 pages of detailed analysis, and were solidly affirmed in many more pages of analysis in three different rulings by three different judges of the United States Court of Federal Claims, and in two rulings by two separate panels of the United States Court of Appeals for the Federal Circuit. The three special master decisions concerning the PSC's *second* theory (concerning vaccinations containing the preservative "thimerosal") were similarly comprehensive.

All told, the 11 lengthy written rulings by the special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit *unanimously rejected* the petitioners' claims, finding no persuasive evidence that either the MMR vaccine or thimerosal-containing vaccines could contribute in any way to the causation of autism.

Thus, the proceedings in the six "test cases" concluded in 2010. Thereafter, the Petitioners in this case, and the petitioners in other cases within the OAP, were instructed to decide how to proceed with their own claims. The vast majority of those autism petitioners elected either to withdraw their claims or, more commonly, to request that the special master presiding over their case decide their case on the written record, uniformly resulting in a decision rejecting the petitioner's claim for lack of support. However, a small minority of the autism petitioners have elected to continue to pursue their cases, seeking other causation theories and/or other expert witnesses. A few such cases have gone to trial before a special master, and in the cases of this type decided thus far, all have resulted in rejection of petitioners' claims that vaccines played a role in causing their child's autism. *See, e.g., Blake v. HHS*, No. 03-31V, 2014 WL 2769979 (Fed. Cl. Spec. Mstr. Vowell May 21, 2014) (autism not caused by MMR vaccination); *Henderson v. HHS*, No. 09-616V, 2012 WL 5194060 (Fed. Cl. Spec. Mstr. Vowell Sept. 28, 2012) (autism not caused by pneumococcal vaccination); *Franklin v. HHS*, No. 99-855V, 2013 WL 3755954 (Fed. Cl. Spec. Mstr. Hastings May 16, 2013) (MMR and other vaccines found not to contribute to autism); *Coombs v. HHS*, No. 08-818V, 2014 WL 1677584 (Fed. Cl. Spec. Mstr. Hastings Apr. 8, 2014) (autism not caused by MMR or Varivax vaccines); *Long v. HHS*, No. 08-792V, 2015 WL 1011740 (Fed. Cl. Spec. Mstr. Hastings Feb. 19, 2015) (autism not caused by influenza vaccine); *Brook v. HHS*, No. 04-405V, 2015 WL 3799646 (Fed. Cl. Spec. Mstr. Hastings May 14, 2015) (autism not caused by MMR or Varivax vaccines); *Holt v. HHS*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. Vowell June 24, 2015) (autism not caused by Hepatitis B vaccine); *Lehner v. HHS*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. Vowell July 22, 2015) (autism not caused by influenza vaccine); *Miller v. HHS*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Vowell August 18, 2015) (ASD not caused by combination of vaccines); *Allen v HHS*, No. 02-1237V, 2015 WL 6160215 (Spec. Mstr. Vowell Sept. 26, 2015) (autism not caused by MMR vaccination); *R.K. v. HHS* (Spec. Mstr. Vowell Sept. 28, 2015) (not yet published) (autism not caused by influenza vaccine) (on appeal); *Hardy*

v. HHS, No. 08-108V, 2015 WL 7732603 (Fed. Cl. Spec. Mstr. Hastings Nov. 3, 2015) (autism not caused by several vaccines).

In addition, some causation autism claims have been rejected *without trial*, at times over the petitioner's objection, in light of the failure of the petitioner to file plausible proof of vaccine-causation. *See, e.g., Waddell v. HHS*, No. 10-316V, 2012 WL 4829291 (Fed. Cl. Spec. Mstr. Campbell-Smith Sept. 19, 2012) (autism not caused by MMR vaccination); *Bushnell v.* HHS, No. 02-1648, 2015 WL 4099824 (Fed. Cl. Spec. Mstr. Hastings June 12, 2015) (autism not caused by multiple vaccines); *Miller v. HHS*, No. 06-753V, (Fed. Cl. Spec. Mstr. Hastings Sept. 25, 2012) (autism not caused by DTaP or MMR vaccines); Fesanco *v. HHS*, No. 02-1770V, 2010 WL 4955721 (Fed. Cl. Spec. Mstr. Hastings Nov. 9, 2010); *Fresco v. HHS*, No. 06-469V, 2013 WL 364723 (Fed. Cl. Spec. Mstr. Vowell Jan. 7, 2013); *Pietrucha v. HHS*, No. 00-269V, 2014 WL 4338058 (Fed. Cl. Spec. Mstr. Hastings Aug. 22, 2014). Judges of this court have affirmed the practice of dismissal without trial in such a case. *E.g.*, *Fesanco v. HHS*, 99 Fed. Cl. 28 (Judge Braden affirming).

In none of the rulings since the test cases has a special master or judge found any merit in an allegation that any vaccine can contribute to causing autism.[5]

III

PROCEDURAL HISTORY

On July 6, 2004, Darius and Teresita Canuto ("Petitioners"), acting *pro se*, filed a Short-Form Autism Petition for Vaccine Compensation on behalf of their son, DAC. After filing their petition, from August 2004 through August 2013, Petitioners were represented, at different times, by attorneys Clifford Shoemaker, Thao Ho, and Harry G. Potter. Petitioners' last attorney, Mr. Potter, withdrew as counsel in August 2013, and Petitioners have since then again been proceeding *pro se*.

Subsequent to the filing of their petition, the case was stayed pending the outcome of the above-described OAP "test cases." (*See* Notice Regarding "Omnibus Autism Proceeding" dated 7/22/2004 (ECF No. 2).) On October 4, 2004, Respondent filed a "Rule 4(c) Report" urging that compensation be denied. (ECF No. 6.)

After the proceedings in all of the OAP test cases became final, on January 30, 2013, I issued an order instructing the Petitioners to determine how they wished to proceed in this case. (*See* Order dated January 30, 2013 (ECF No. 16).) After their final attorney's motion to withdraw from the case was granted on August 22, 2013, I again issued to Petitioners orders

[5] In *Wright v. HHS*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015), Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a "Table Injury" after a vaccination. However, she stressed that she was *not* finding that the vaccinee's ASD in that case was "caused-in-fact" by the vaccination--to the contrary, she specifically found that the evidence in that case did *not* support a "causation-in-fact" claim, going so far as to remark that the petitioners' "causation-in-fact" theory in that case was "absurd." 2015 WL 6665600, at * 2.

instructing them to inform me of how they wished to proceed, and to file medical records pertaining to DAC if they wished to pursue their case. (*See* Orders dated August 22 and 27, 2013, ECF Nos. 26, 27.) On November 13, 2013, Petitioners filed Exhibits 1 to 84, consisting chiefly of DAC's medical records. (ECF No. 30.)

On January 2, 2014, Respondent filed a statement addressing whether this claim should proceed. (ECF No. 33.) Respondent stated that Petitioners had not identified which vaccines injured DAC, or when the alleged injury began. (*Id.*) On January 24, 2014, Petitioners filed a response, addressing the first sign or symptom of DAC's injury. (ECF No. 35.)

Subsequently, on October 1, 2014, Petitioners filed, without exhibit numbers, both an expert report by Dr. Mark Levin, M.D. (herein after "Levin Report"), as well as his *curriculum vitae* (hereinafter "Levin CV"). (ECF No. 44.) On December 10, 2014, Respondent filed an expert report by Dr. Max Wiznitzer, along with medical literature. (Exhibits A-F.)[6]

On December 19, 2014, Petitioners filed a document titled "Theory of Causation." The document was divided into ten parts labeled Exhibits I to IX, along with a final section titled "Recapitulation."[7]

On January 7, 2015, I ordered Petitioners to file a written submission indicating whether they wished for me to issue a causation decision based on the written record, or whether they would like to propose some other procedure. (*See* my Inquiry to Petitioners, filed January 7, 2015 (ECF No. 49).) Petitioners subsequently requested a ruling on the record, without an evidentiary hearing. (*See* "Request to Issue a Decision," filed January 15, 2015 (ECF No. 52).)

On April 2, 2015, Petitioners filed additional medical literature and inquired about the status of their case.[8] (ECF No. 51.) On April 8, 2015, I issued an Order responding to Petitioners' "Inquiry" of April 2, 2015. I noted that I had waited more than a decade for Petitioners to present evidence to support their case, and would consider the evidence they filed on April 2. (ECF No. 53).

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[6] Respondent filed these materials on compact disc. Respondent's filing made on December 10, 2014, is incorrectly listed on the docket at ECF No. 48 as "Theory of Causation for exhibits 1-9 on Compact Disc." The latter description, however, refers to Petitioners' filing of December 19, 2014, for which there is no other docket entry.

[7] The "Theory of Causation" filing made by Petitioners on December 19, 2014, consists of over 400 pages. Although the document does contain some pages from DAC's medical records, it mostly consists of a collection of excerpts Petitioners copied from various sources (often Wikipedia) interspersed with Petitioners' own commentary regarding the alleged significance of the collected excerpts, mostly as they relate to further allegations regarding DAC and various aspects of his medical profile (*e.g.*, blood type, genetic profile, etc.).

[8] This filing included documents similar in nature to the ones filed on December 19, 2014, (*see* fn. 7, above) though much shorter at 62 pages. It was accompanied by about ten medical articles which Petitioners submitted in full, though without exhibit designation. The document itself is dated March 31, 2015, though it was not received by the Court until April 2, 2015.

On August 7, 2015, Petitioners filed a document they titled "Focus of Review." (ECF No. 57.) Attached to the document were many more pages of additional materials.[9]

On September 11, 2015, Petitioners filed an additional inquiry requesting that their case be decided promptly. This request was titled as a "Request to Issue a Final Decision."[10] (*See* Motion, September 11, 2015 (ECF No. 58).)

IV

FACTS

A. Medical records

DAC was delivered via caesarean section on July 17, 2000, in Bocaue, Philippines, after a full-term pregnancy. (Ex. 4 at 1; Ex. 11, p. 1.) DAC vomited in the first hours of life and showed mild jaundice. (Ex. 11, pp. 3-4.) He was discharged after three days. (*Id.*, p. 4.)

DAC's early pediatric care through his fifth month of life was provided by Dr. Gonzales of Bocaue, Philippines.[11] (Ex. 13, p. 3.) Dr. Gonzales noted DAC to be a "well baby" during his pediatric visits on August 26, 2000, September 26, 2000, and October 25, 2000. (*Id.*, p. 1.) The only complaint identified by Dr. Gonzales was an early bout of lactose intolerance remedied by a switch to lactose-free formula. (*Id.*, p. 3.) Significant to this case, among the early childhood vaccines administered by Dr. Gonzales were two doses of "Tritanrix" on September 26, 2000 and November 23, 2000. (*Id.*, pp. 1-2.) Dr. Gonzales identified the Tritanrix vaccine as a combined "DPT" (diphtheria, tetanus and whole-cell pertussis) and "Hep B" (hepatitis B) vaccine.[12] (*Id.*, p. 1.)

Subsequently, from January 2001 through March of 2001, DAC was under the pediatric care of Dr. Teresita Tan, in Los Angeles, California. (Ex. 15.) During this period he was treated for a number of illnesses, including an upper respiratory infection on January 6, 2001, and

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[9] This filing includes excerpted pages from the prior filings referenced. It also includes many pages devoted to photographs of holes in the walls and ceiling of, apparently, Petitioners' apartment. There is no explicit allegation that these photographs are in any way related to DAC's vaccine injury claim, nor any explanation of how they could be relevant to Petitioners' claim.

[10] I am sorry that I was not able to file this Decision sooner than I have, subsequent to Petitioners' "Request to Issue a Decision," filed on January 15, 2015. However, I must note that when Petitioners thereafter filed *additional* materials, apparently intended to support their causation claim, on both April 2, 2015, on August 17, 2015, I was thereby required to review both of those sets of additional materials before issuing this Decision.

[11] The records provided for Dr. Gonzales (Ex. 13) appear to be an after-the-fact summary of Dr. Gonzales's treatment, written in October of 2013; however, DAC's pediatric visits with Dr. Gonzales also appear to be recorded in a baby book maintained by petitioners. (Ex. 12.)

[12] Dr. Gonzales's records also indicate that DAC received a dose of "BCG" (a type of tuberculosis vaccine), two doses of "OPV" (oral polio vaccine), and two doses of "Hib" (Haemophilus influenza type B). (Ex. 13, pp. 1-2.)

bronchitis on February 5, 2001. (*Id.*, pp. 2-3.) On January 26, 2001, Dr. Tan administered a "Dtap" (diphtheria, tetanus, and acellular pertussis)[13] vaccine as well as an "IPV" (inactivated polio) vaccine, which was noted as his third dose. (*Id.*, pp. 1, 3.) On March 30, 2001, Dr. Tan administered DAC's third dose of Hib vaccine. (*Id.*, pp. 1, 5.)

Thereafter, DAC began seeing Dr. Gladys Hope Yerro for his pediatric care through the end of 2002. (Exs. 16-20.) His first visit with Dr. Yerro was a sick visit on April 4, 2001, approximately five days after his March 30 Hib vaccination. (Ex. 16.) DAC presented with two days of fever; he also had a cough and cold. (*Id.*, p 1.) His symptoms were attributed to otitis media (ear infection).[14]

Dr. Yerro next saw DAC on August 3, 2001, for a one-year well check-up.[15] (Ex. 17.) Her developmental notes indicate that DAC was saying "Dada" and "Baba" and was cruising or walking with support, but that he had poor weight gain and was "lagging behind" on speech and language milestones.[16] (*Id.*, pp. 1-2.) Dr. Yerro observed that DAC was negative for vaccine reactions. (*Id.*, p. 1.) He received MMR and varivax vaccinations at this visit. (*Id.*, p. 2.)

DAC was seen again by Dr. Yerro on October 31, 2001, for acute gastroenteritis, and on November 19, 2001, for an upper respiratory infection. (Exs. 18-19.) On December 3, 2001, DAC was seen with one week of coughing, three nights of waking, and constipation. (Ex. 20.) At 16 months of age, Dr. Yerro noted that DAC's development was limited to one word, "daddy." (*Id.*, p. 1.) Dr. Yerro wrote that DAC "needs to stim[ulate] verbally, advised should have [at] least 10-15 words." (*Id.*, p. 2.) At this visit DAC also received Hib and DTaP vaccinations. (*Id.*) Dr. Yerro again recorded that DAC had not experienced any vaccine reactions. (*Id.*, p. 1.)

Medical records for the years 2002 and 2003 are sparse. DAC was tested for tuberculosis in March of 2002. (Ex. 24.) He received a Hepatitis A immunization on July 18, 2002, and was seen for acute gastroenteritis on July 30, 2002. (Exs. 25-26.) His vision and hearing were tested on August 27, 2002, and he underwent a dental extraction under anesthesia in December of 2002. (Exs. 28-29.) None of these records address DAC's growth and development.

On July 7, 2003, DAC was evaluated for a preschool pre-admission physician's report. DAC was noted to have a "slight" developmental delay as well as "delayed speech." (Ex. 30, p.

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[13] Subsequent vaccination records which purported to "copy" DAC's prior vaccinations incorrectly identified this January 26, 2001 vaccination as being a "DPT" vaccine (Ex. 14; Ex. 27, pp. 1, 3); however, I accept Dr. Tan's record as accurate (*see* fn. 23, below).

[14] In fact, the record says the impression is "om." This is a commonly used abbreviation for "otitis media." *See, e.g.*, N.M. Davis, Medical Abbreviations: 32,000 Conveniences at the Expense of Communication and Safety (15th ed.), p. 239. Mrs. Canuto likewise confirmed that she understood DAC to have been diagnosed with otitis media at that visit. (Ex. 21, p. 2.)

[15] DAC's vaccination record from Dr. Yerro indicates that DAC received a pneumococcal vaccine and a Hepatitis B vaccine on May 3, 2001 (Ex. 22; Ex. 14, pp. 1-2); however, no record for this visit was filed.

[16] Significantly, DAC was raised in a bilingual home. Subsequent records indicate an increased effort to adjust to speaking English in the home when DAC was over 3 years old. (*See, e.g.,* Ex. 39, p. 1.)

1.) At that time, DAC also received his second Hepatitis A vaccination. (*Id.*, p. 3; Ex. 31.) On September 17, 2003, DAC was treated for an upper respiratory infection. (Ex. 32.)

Subsequently, a speech/language evaluation on October 30, 2003, indicated that "since infancy, the patient has had no significant medical conditions. With the exception of speech and language development, the patient's early developmental milestones were within normal limits. The patient babbled as an infant, when he was not developing language by 2- ½ years, his parents grew concerned. He has about 40 words in his expressive vocabulary and he does not use 2-word combinations." (Ex. 34 at 1.) Moreover, on the Preschool Language Scale 3 (PLS-3), the auditory comprehension standard was 56, and expressive communication was 62. (*Id.*) DAC had the ability to initiate a game or social routine. (*Id.*) DAC was diagnosed with severe to profound expressive and receptive language disorder. (*Id.* at 2.)

During a preschool assessment on January 24, 2004, his teacher wrote that DAC was below 18 months on expressive and receptive language. (Ex. 35 at 2.) Additionally, he did not speak during the assessment, and his eye contact was fleeting. (*Id.* at 3.) On February 7, 2004, DAC had an Individualized Education Program (IEP), which reported that he had attention deficit with speech and language delays. (Ex. 36 at 5.) His assessment stated "severe receptive and language delay will impact his ability to assess language-based on activities of the preschool curriculum." (*Id.*)

On March 15, 2004, DAC was evaluated by a developmental behavioral pediatrician, Nancy Brill, M.D. (Ex. 39 at 1.) Her history indicated that he smiled at five months, cooed at six months, and that by age three years and eight months he had attained a vocabulary of about sixty words. (*Id.*) By the time of his evaluation, DAC was beginning to form two-word phrases. (*Id.*) On the Gesell Developmental Testing, his developmental age was 30.4 months at the chronological age of 44 months. (*Id.* at 3.) Dr. Brill diagnosed DAC with autism due to his delayed language skills, difficulty interacting with peers, and limited play skills. He also displayed repetitive behavior like tightening his fists and echo speech. (*Id.*) Subsequent genetic testing showed no chromosomal abnormality. (Ex. 40.) DAC later had a follow-up appointment with Dr. Brill at four years of age on November 19, 2004. (Ex. 42.)

No medical records have been filed for the period from November of 2004 until October of 2005, other than records for twelve speech therapy sessions from July through October of 2005. (Ex. 47.) Although DAC made some progress, his speech therapy was ended at his mother's request. (*Id.*, p. 7.) Upon discharge from speech therapy, DAC still had a "severe" receptive and expressive language disorder. (*Id.*) DAC underwent a number of educational evaluations during this period as well. (Exs. 44-46, 48.)

During his pediatric visit on October 19, 2005, DAC was noted to have had a history of autism and febrile seizures, with the "last one 1 year ago." (Ex. 49 at 1.) He could count and spell. (*Id.*) DAC received occupational therapy at school. His mother declined vaccines because she remarked that they "make him sick." (*Id.*)

In March of 2006, DAC underwent a psychoeducational assessment at five years of age to reevaluate his eligibly for special education services. (Ex. 53.) This assessment confirmed his

prior autism diagnosis. (*Id.*, p. 11.) Most of the remaining records filed in this case pertain to further educational assessments or other academic reports. (*See* Exs. 56, 59-61, 64-65, 67-72, 75, 77-83.) Petitioners also filed blood and urine test results from October 2006 from The Lord's Hospital in Bulacan, Philippines, for which there are not correlating progress notes or other records of any medical visit. (Exs. 57-58.)

A child "well visit" on August 15, 2008, noted that DAC no longer was receiving speech therapy. (Ex. 63 at 2.) At that time it was also noted that DAC's "teachers were concerned that they were seeing him have a 'tremor' towards the end of the school year." (*Id.*) Although DAC's parents at that time gave a history of seizures from eight months to four years of age, it was noted of the tremor complaint that "they have not seen this at home." (*Id.*) It was further noted in the medical record that "they say he used to do some hand flapping and shaking when younger but nothing in several years." (*Id.*) DAC's physician felt the shaking was a "behavioral action," but recommended a neurological follow up in light of the reported history of seizures. (*Id.*, p. 3.) Follow-up EEG testing on January 9, 2009, was interpreted as abnormal, showing "occasional right central/parietal sharps" suggestive of "an increased risk of focal onset seizures." (Ex. 66, p. 2.) However, "clinical correlation" was recommended, and the history of tremor episodes was considered "poorly described." (*Id.*, pp. 1-2.)

In June of 2011, DAC underwent genomic testing for mitochondrial disorders. (Ex. 74.) The results were negative. (Ex. 74, p. 1.)

B. Parental statements and affidavit

In an affidavit, Mrs. Canuto averred that DAC had a fever, cough, and loss of appetite, after his Hib vaccination of March 30, 2001. (Ex. 21 at ¶ 3.) She said that on the evening of April 3, 2001, she saw "for the first time his arms, head, legs jerked, there was uncontrollable muscle spasm occurred in his body in an awake state." (*Id.* at ¶ 4.) Although she stated that she didn't know it at the time, Mrs. Canuto alleged that what her son experienced was a seizure. (*Id.*, ¶ 5.) Additionally, a narrative prepared by Petitioners for this claim stated that on March 30, 2001, after the Hib vaccination, DAC had a fever of 103.2 degrees for two days, and had "convulsions with a cough/ cold for a week." (Ex. 41, p. 1.)

Ms. Canuto further averred in her affidavit that DAC had seizures on November 19, 2001, June 5, 2002, July 30, 2002, September 30, 2002, December 28, 2002, April 14, 2003, September 17, 2003, and September 5, 2004. (Ex. 21, ¶¶ 12-14.) Additionally, she stated that the seizure of September 5, 2004, was DAC's last. (*Id.* at ¶ 14.)

Petitioners also submitted excerpts from a daily planning diary they maintained. (Ex. 84.) These pages indicate that Petitioners tracked DAC's medical appointments and some of DAC's illnesses, including recording his various fevers. (*Id.*) Although somewhat difficult to read, I do not see any reference to seizures or seizure-like symptoms recorded in these entries. (*Id.*)

At least two of these alleged seizures, including the one that Petitioners link to DAC's Hib vaccination on March 30, 2001, coincide with illnesses for which DAC was treated by his pediatricians. In fact, Mrs. Canuto indicated in her affidavit that the seizure was the primary

purpose of DAC's April 4, 2001, appointment with Dr. Yerro. (Ex. 21, ¶ 7.) Yet DAC's contemporaneous medical records do not indicate any report of seizures or seizure-like symptoms at that time. (*See,* Exs. 16, 19.) As noted above, DAC's seizures were first addressed in the medical records on October 19, 2005. (Ex. 49, p. 1.) At that time, no specifics were indicated regarding onset or frequency, only that the last one occurred approximately a year prior. (*Id.*) A much later record in 2008 identified seizures beginning at eight months of age, but this was simply a notation of a parental report which was offered, as with Mrs. Canuto's affidavit, years after the fact. (Ex. 63, p. 2.) Significantly, an evaluation in October of 2003 reported that "since infancy, the patient has had no significant medical conditions." (Ex. 34 at 1.)

Medical records "warrant consideration as trustworthy evidence." *Cucuras v. Sec'y of Health & Human Servs.,* 993 F.2d 1525, 1528 (Fed.Cir.1993). Accordingly, where subsequent testimony conflicts with contemporaneous medical records, special masters frequently accord more weight to the medical records. *See, e.g., Reusser v. Sec'y of Health & Human Servs.,* 28 Fed. Cl. 516, 523 (1993) ("[W]ritten documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later."). To the extent that DAC's contemporaneous medical records show no report of any seizures or seizure-like symptom, this suggests that Mrs. Canuto's much later affidavit should not be credited with regard to DAC's alleged seizures.

To be sure, I do note that Mrs. Canuto indicates that she did not know at the time that what she was describing was a seizure, describing it instead as uncontrollable muscle spasms including the jerking of the arms, head and legs. (Ex. 21, p. 1.) Moreover, later medical records do *retroactively* reference the history of seizures that Mrs. Canuto alleges. In that regard, "it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant." *Murphy v. HHS*, 23 Cl. Ct. 726, 733 (Fed. Cl. 1991), *aff'd,* 968 F.2d 1226 (Fed. Cir. 1992).

In balancing these considerations in this case, I do *not* credit Mrs. Canuto's report of seizure activity occurring between April of 2001 and September of 2004. That a pediatrician would not recognize and not record a description of a seizure in one instance would be unusual enough.[17] In this case, however, Mrs. Canuto contends that DAC experienced seizures on nine separate occasions throughout that three-plus year period. (Ex. 21, p. 2.) Yet I do not find a single *contemporaneous* reference in DAC's medical records to seizures, or any description of symptoms similar to the muscle spasms and jerking that Mrs. Canuto describes. This is particularly significant in that DAC's seizures allegedly occurred, on at least two occasions, at or around the time of pediatric *sick visits*. Nor are these seizures reflected in Petitioners' own diary entries which otherwise recorded DAC's illnesses, including the illness that allegedly triggered the first seizure, which was recorded only as "got fever/cough." (Ex. 84, p. 2.) Moreover, the earliest reference to seizure activity in the medical records in 2005, which is silent regarding the

[17] Despite not recognizing it as a seizure, Mrs. Canuto indicated that she did, in fact, report DAC's April 2001 spasms to his pediatrician. (Ex. 22, p. 1.)

onset of this seizure activity, post-dates the October 2003 evaluation which included a report that DAC had had *no serious medical issues since infancy.*

Nor is the much later 2008 parental report of early childhood seizures persuasive corroboration. At that time DAC was evaluated regarding "tremors" noted by his teachers. Although DAC's parents at that time gave a history of seizures from eight months to four years of age, which report ultimately led to an abnormal EEG result, it was noted of the tremor complaint that "they have not seen this at home." (Ex. 63, p. 2.) And indeed, Mrs. Canuto's affidavit does appear to treat the alleged earlier seizures as distinct from later tremors. (Ex. 21, pp. 2-3.) It was further noted in the medical records that "they say he used to do some hand flapping and shaking when younger but nothing in several years." (Ex. 63, p. 2.) And, in any event, this report, like Mrs. Canuto's affidavit, came only years after the fact.

Although DAC's medical records from 2005 and 2008, and particularly the EEG results, suggest that DAC may have experienced seizures during those years, they do *not* lend any support to Mrs. Canuto's contention that he was experiencing seizures from around eight months of age to about four years of age, let alone that seizures occurred on each of the specific dates alleged. Thus, I decline to accept as accurate Mrs. Canuto's after-the-fact recollection that DAC experienced seizures between April of 2001 and September of 2004. Her recollection is not consistent with the contemporaneous medical records.

C. Additional family statements

Petitioners also submitted several statements by family members, specifically three aunts, describing observations they had made concerning DAC's behavior and development. Maria Concepcion C. Lim noted that on December 25, 2001, DAC was delayed in speech, walking, and understanding. (Ex. 21, p. 4.) Teresita C. Tibajia stated that she noticed that DAC was not developing like her own children. (*Id.*, p. 5.) She noted that he did not walk until 17 months, and that he could not say her name, did not respond to his own name, used repetitive language, and could not converse with people. (*Id.*) Both aunts characterized DAC as appearing "like any other child" at about five months of age. (*Id.*, pp. 4-5.) Virginia C. Cunanan stated that "He has some uncontrolled behavior such as running straight when playing. He doesn't pay attention when he is being called. He was very aloof and ignores the person who was talking to him." (*Id.*, p. 6.) Ms. Cunanan's statement did not address the onset of those behaviors.

Although I have considered these statements, I do not find them helpful in resolving this case. None of the details recalled by these family members leaves either party's theory more or less likely to be correct.

V

SUMMARY OF EXPERT WITNESSES' QUALIFICATIONS AND OPINIONS

In this case, Petitioners presented an expert report of one medical expert; respondent also presented an expert report of one medical expert. At this point, I will briefly summarize both the qualifications and the opinions of these expert witnesses.

A. Petitioners' expert, Dr. Mark Levin

1. Qualifications

Petitioners rely on the expert report of Dr. Mark Levin. Dr. Levin attended Yeshiva University, earning a Bachelor of Arts degree in 1980. (Levin CV, p. 1.) He graduated from SUNY- Downstate Medical College in 1984 with a degree in medicine. (*Id.*) During his postgraduate training, he was an intern and then resident in internal medicine at New York Downtown Hospital in New York, New York from 1986-1987. He is licensed in New York (1990) and New Jersey (2000). (*Id.*) He was certified by the American Board of Internal Medicine in 1987, and later certified in Oncology in 1989, and Hematology in 1990.[18] (*Id.*) Currently, he is the acting chief of hematology and oncology at the University of Medicine and Dentistry of New Jersey- Newark. (*Id.* at 1.) He has authored 23 articles, several book chapters, and 10 abstracts, which are listed on his CV (*Id.* at 11-15.)

2. Summary of Dr. Levin's opinion

Dr. Levin's report indicated that he believes that DAC's DTP vaccines caused him to suffer fever, seizures, and encephalitis, thereby causing autism.[19] (Levin Report, p.3.) He contended that the temporal relationship between the first symptoms of DAC's autism and the administration of DTP vaccine is consistent with reports from literature.[20] (*Id.*) He further contended that vaccine causation is supported by the fact that there is an otherwise unexplained increase in autism rates in the United States. (*Id.*) Dr. Levin also cited unspecified court cases in which Pervasive Developmental Disorder ("PDD"), a condition on the autism spectrum, has allegedly been associated with vaccines, and in which individuals have been compensated in this Program for injuries caused by DTP and DTaP vaccines. (*Id.*, pp. 3-4.)

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[18] Dr. Levin's certification in Hematology is marked as "re-certification required" without any reference to recertification since 1990. (*Id.*)

[19] Dr. Levin did not specifically identify which of DAC's DTP vaccines he believed to be casual. In his summary of DAC's medical history, he noted that DAC received DTP vaccinations on September 26, 2000, November 23, 2000, and January 26, 2001. (Levin Report, p. 2.) The vaccination of January 26, 2001, however, was actually a DTaP vaccination and not a DTP vaccination as Dr. Levin stated in his report. (*See* fn. 21, below.)

[20] Dr. Levin did not specify what literature he was referencing. Nor did he define or give a time frame for what he considered to be a temporal relationship. Moreover, since he did not identify which specific vaccine(s) out of DAC's series of DTP vaccines he believed to be causal, he did not actually either explicitly or implicitly identify the actual period of onset in DAC's own case.

Ultimately, Dr. Levin opined that "I do not consider the MMR vaccine to be causative in this case, since the first symptoms of autism were noted on the same [date] that MMR was administered. However, DTP appears to have caused fever, seizures and encephalitis in this case, which has been related to later development of autism." (*Id.*, p. 4.) However, Dr. Levin did not explain or substantiate his contention that encephalitis "has been related to later development of autism." Nor did he describe what he considers to constitute the onset of DAC's alleged encephalitis.

B. Respondent's expert, Dr. Max Wiznitzer

1. Qualifications

Respondent relies on the expert report of Dr. Max Wiznitzer. Dr. Wiznitzer attended the Northwestern University Honors Program and specialized in Medical Education, earning a Bachelor of Science degree in Medicine in 1975. (Ex. B, p. 1.) Dr. Wiznitzer later graduated from Northwestern University Medical School in 1977 with a degree in medicine. (*Id.*) During his postgraduate training, Dr. Wiznitzer was a resident in pediatrics at the Children's Hospital Center in Cincinnati, Ohio from 1977 to 1980. (*Id.*) He also was a fellow in developmental disorders at the Cincinnati Center for Developmental Disorders from 1980 to 1981. (*Id.*) He thereafter became a fellow in pediatric neurology at the Children's Hospital of Philadelphia from 1981 to 1984. (*Id.*)

Dr. Wiznitzer was certified by the American Board of Pediatrics in 1982, the American Board of Psychiatry and Neurology in Child Neurology in 1986, and the National Board of Medical Examiners in 1978. (*Id.*, p. 5.) He has been licensed in Ohio (1979), Pennsylvania (1981), and New York (1984.) (*Id.*) Since 1986, Dr. Wiznitzer has rotated between Assistant Professor of Pediatrics, Neurology, and International Health at Case Western Reserve University. (*Id.*, p. 2.) He has also had a number of hospital appointments, including most notably 19 years as either director or co-director of the Rainbow Autism Center at Rainbow Babies and Children's Hospital in Cleveland, Ohio. (*Id.*, p. 3.)

Dr. Wiznitzer has also served on the editorial boards of many journals, including *Pediatric Neurology, Journal of Child Neurology, and Lancet Neurology.* (*Id.* at 6.) He has authored or co-authored 68 original journal articles, 11 book chapters, and 55 abstracts, which are listed on his CV. (*Id.* at 13-23.)

2. Summary of Dr. Wiznitzer's opinion

Dr. Wiznitzer asserted that DAC's clinical course is consistent with ASD, and that he displayed a "typical developmental trajectory" for a child with ASD. (Ex. A, pp. 5-6.) Specifically, Dr. Wiznitzer described a slow acquisition of language skills, with a gradual appearance of social differences, and no reported history of regression. (*Id.*) Dr. Wiznitzer stated that there is no evidence in the contemporaneous medical records of DAC having a seizure, acute encephalopathy, or encephalitis following any DTP vaccination. (*Id.*, p. 6.) He further noted that the medical records specifically note the absence of any history of vaccine reactions, on August 3, 2001, and December 3, 2001. (*Id.*)

Dr. Wiznitzer also characterized Dr. Levin's theory as "speculative and without biological plausibility or scientific basis." (*Id.*) Dr. Wiznitzer noted that, in addition to finding no support for his assertions in DAC's medical records, Dr. Levin offered no mechanism of injury, and further that, in fact, Dr. Levin "offers no causal theory whatsoever." (*Id.*) Dr. Wiznitzer disputed Dr. Levin's assertion of an association between autism and DTP, noting that the epidemiological evidence, to the contrary, favors *rejection* of an association between autism and thimerosal-containing vaccines, which he indicated includes DTP vaccines. (*Id.*)

VI

ISSUES TO BE DECIDED

Unfortunately, despite my order to do so (ECF No. 16), Petitioners never filed an amended petition for this case. Therefore, the only petition in the record is Petitioners' short-form Autism Petition. That Petition invokes the Master Autism Petition, which in turn alleges that "the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was caused by a measles-mumps-rubella (MMR) vaccination; by the 'thimerosal' ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two."

Nonetheless, as noted in the procedural history above, Petitioners have submitted unorthodox filings in this case containing expansive allegations regarding DAC, his vaccinations, and his alleged injury. Specifically, Petitioners' Exhibit IV identifies the following vaccinations as causal of DAC's injury: Inactivated Polio Virus vaccine (IPV) and Diphtheria Tetanus and Acellular Pertussis vaccine (DTaP), both administered January 26, 2001; Haemophilus Influenzae B Conjugate vaccine (HIB3), administered March 30, 2001; Hepatitis A vaccine, administered March 30, 2001; and Measles, Mumps and Rubella live virus vaccine (MMR) and Varicella virus vaccine, both administered August 3, 2001. (Ex. IV, p. 2.)

Petitioners' submissions also discuss many concepts related to a variety of subject areas, including, *inter alia*, metabolism, immune response, allergy, inflammation, genetics and enzymology, which they believe are relevant to establishing that these vaccines caused their son's autism. They do not, however, specify the exact nature of DAC's alleged injury, referring instead to "DAC's ASD (Autism Spectrum Disorder) or other injury." (Ex. I, p. 3.)

However, the *expert report* that Petitioners subsequently filed in this case, in contrast to Petitioners' own expansive claims, opines *only* that DAC's series of *DTP vaccinations* caused his injury. (Levin Report, pp. 2-3.) Dr. Levin explicitly opined that the MMR vaccine did not cause DAC's injury. (*Id.*, p. 4.) Specifically, Dr. Levin opined that "DTP appears to have caused fever, seizures, and encephalitis in this case, which has been related to later development of autism." (*Id.*, p. 4.)

As described in the following section of this Decision, Petitioners' own multiple submissions do not constitute substantial or persuasive evidence in this case. Nor do any of DAC's medical records suggest that any of his vaccinations caused his autism. Therefore,

notwithstanding the broad allegations contained in Petitioners' own submissions, the issue to be decided in this case is effectively limited to whether Petitioners have established it to be "more probable than not" that DAC's *DTP vaccinations* caused an encephalitis or encephalopathy resulting in autism, as their medical expert opined. This is the only claim which can fairly be said to have been prosecuted through the submission of minimal medical evidence.

Respondent, through submission of an expert report by Dr. Max Wiznitzer, disputed that DAC's autism was caused by his DTP vaccinations, or any other vaccinations. (Ex. A, pp. 6-7.) Rather, Dr. Wiznitzer opined that DAC followed "an expected developmental trajectory" for a child with ASD, and that there is no evidence of encephalitis or encephalopathy. (*Id.*, p. 6.)

For the reasons described below, I have concluded that Petitioners have not presented a claim for which relief can be granted under the Vaccine Act, and that, in any event, Petitioners' expert was utterly unpersuasive in his contention that DAC experienced a vaccine-caused injury.

VII

PETITIONERS' MULTIPLE SUBMISSIONS REGARDING THEIR THEORY OF CAUSATION

Before considering the expert opinions in this case, I turn first to the multiple submissions provided by the Petitioners themselves, which were noted in the procedural history above. This case is unique in that Petitioners have expended a great amount of effort in submitting many hundreds of pages of explanation regarding their own personal views of how DAC's vaccinations might have caused his injury. These submissions are a clear reflection of Petitioners' deep-seated conviction that DAC's current condition is the result of his vaccinations. Nonetheless, I note that the views expressed in these submissions do not constitute a *medical* or *expert* opinion in support of vaccine-causation. They therefore have very little evidentiary value, and are of little benefit in deciding this case.

The Vaccine Act states that "[t]he special master or court may not make such a finding [of eligibility and compensation] based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." § 300aa-13(a)(1). Obviously, these documents were created by Petitioners themselves, who have not demonstrated that they are qualified to offer medical opinions.[21] (*See, e.g.*, Ex. I, pp. 2-3 (indicating that the "Theory of Causation"

[21] I do note that Mrs. Canuto's affidavit indicates that she is currently a nurse, though she does not identify her training or any certifications. (Ex. 21, p. 1.) Nor would it seem that she has had a long career as a nurse. She averred that she did not have any medical background at the time of the alleged onset of DAC's injury. (*Id.*) Indeed, DAC's birth certificate indicates that, at least as of that date, Mr. Canuto was a "businessman" and Mrs. Canuto was a "government employee." (Ex. 4.) There is nothing further in the record of this case to suggest that either Mr. or Mrs. Canuto has any medical training. Although Mrs. Canuto's nursing background may have provided her with some basic grasp of medical concepts and terminology, a nurse is generally not qualified to offer an opinion regarding the *causation* of medical conditions, and the content of Petitioners' submissions touches little, if at all, on subjects actually related to nursing. Indeed, the assertions made in these submissions extend well beyond anything that could reasonably be considered within the training and experience of a nurse. Moreover, even if a nurse could be considered qualified to render a medical opinion in certain circumstances, there is nothing in the record that

document was prepared by petitioner Teresita Canuto).) Petitioners simply are not qualified to make the assertions contained in these documents regarding either the significance of DAC's own medical records or the various other materials cited. (*See, e.g., Dickerson v. HHS*, 35 Fed. Cl. 593 (1996), explaining that even in a Table Injury case, a medical opinion is still necessary to categorize the reactions described by petitioner as actual symptoms or manifestations of the alleged injury.) These documents therefore do not constitute persuasive evidence, especially when weighed against the contrary opinion of Respondent's pediatric neurologist, Dr. Wiznitzer.

Petitioners were advised multiple times that in order to succeed on their claim it would have to be supported by the opinion of a medical doctor indicating that DAC's autism was, "more likely than not," caused by his vaccinations. (*See, e.g.,* Scheduling Order, April 11, 2014 (ECF No. 36); Order, August 22, 2013 (ECF No. 26).) Petitioners have supplied a medical expert's report, from Dr. Levin, but that expert report only implicates DAC's series of *DTP* vaccinations. (*See* Levin Report, *generally.*) Additionally, Dr. Levin's report does *not* offer any support to the diverse assertions made in Petitioners' own submissions. Whereas Dr. Levin cited the DTP vaccines as causal, Petitioners' submissions do not list the DTP vaccines as causal, instead listing many other vaccines. (See, *e.g.,* Ex. IV, p. 2.)

To the extent that Petitioners' submissions cobbled together excerpts from medical literature, those articles have not been filed into the record of this case. Moreover, the excerpts are presented without their full and proper context. I am therefore unable to assess the merits of any of the cited work. Further, it is quite likely that many, if not most, of the studies cited were *not* conducted with regard to determining a potential link between vaccinations and autism. To the extent that Petitioners would seek to extend that work into a new and different context, such extension would have to be supported by expert medical opinion. Yet, despite the fact that Petitioners have indicated that they provided these materials to their expert, the theory of causation they describe is far afield of anything discussed or cited by Dr. Levin. Rather, the record suggests that Petitioners' own expert, by declining to include Petitioners' theories of causation in his report, effectively *rejected* Petitioners' views regarding causation.

The same issue exists in regard to the ten medical articles which Petitioners did file in full. (*See* ECF No. 51.) I have reviewed all of these articles and I do not find them helpful in resolving this case. None of these articles were cited by Petitioners' expert, and all of the articles appear to me to be entirely irrelevant to Petitioners' claim.

Even considering Petitioners' submissions as evidence, I am compelled to note that, despite what appears to have been great effort on Petitioners' part, these submissions remain largely, if not entirely, incoherent, and are completely unpersuasive. Again, what Petitioners describe in these filings is far removed from anything addressed by their expert, and appears extremely implausible. Moreover, most of the assertions made regarding DAC are not supported by the medical records, and are entirely speculative. Significantly, none of DAC's medical records attribute his autism to *any* of his vaccinations.

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actually substantiates Mrs. Canuto's nursing background or otherwise speaks to the extent and quality of her training or experience.

This leaves Dr. Levin's report, which implicates DAC's series of *DTP vaccines*, as the only potentially viable path for Petitioners to establish that their son's autism was, more likely than not, caused by his vaccinations. Despite Petitioners' lengthy submissions, there is nothing in the evidentiary record offering any persuasive support to any other claim.

VIII

ANY INJURY STEMMING FROM DAC'S DTP VACCINES MAY NOT BE COMPENSABLE AS A MATTER OF LAW, BECAUSE THEY WERE NOT ADMINISTERED IN THE U.S.

Turning to Dr. Levin's report, a threshold issue presents itself, in that Dr. Levin's opinion is restricted to DAC's *DTP* vaccinations, which were administered in the Philippines. (*See* Levin Report, p. 3; Ex. 13, pp. 1-3.) This may leave Petitioners without a compensable claim, because the Vaccine Act generally limits compensation to injuries resulting from vaccines received in the United States or its territories. § 300aa-11(c)(1)(B)(i)(I).

Dr. Levin's report indicated that "it is my opinion within a reasonable degree of medical certainty that the DTP vaccine caused [DAC] to develop and manifest autistic spectrum disorder." (Levin Report, p. 3.) He further opined that "I do not consider the MMR vaccine to be causative in this case, since the first symptoms of autism were noted on the same [day] that MMR was administered. However, DTP appears to have caused fever, seizures, and encephalitis in this case, which has been related to later development of autism." (*Id.*)

This matter is unclear, however, since the statue contains two *exceptions* to the general rule that the Program covers only vaccinations administered in the U.S. *See* § 300aa-11(c)(1)(B)(i)(II) and (III). Under subpart III of that statutory section, the Program *does* cover vaccinations received outside the U.S. or its territories *if* --

> the vaccine was manufactured by a vaccine manufacturer located in the United States, and [the vaccinee] returned to the United States not later than 6 months after the date of the vaccination.

In this case, from the filed records it is simply *unknown* whether the particular DTP vaccines that DAC received in the Philippines were covered by the Program or not. If they were *not* manufactured by a manufacturer located in the United States, that would be a reason to deny Petitioners' claim, but the matter is unclear.

Therefore, I will *assume* for purposes of this Decision that DAC's two DTP vaccines in question *were* covered by the Program. Even under that assumption, however, Petitioners' causation claim *still fails*, for reasons set forth below.

IX

DR. LEVIN'S MISTKEN ASSUMPTION ABOUT DAC'S VACCINATION OF JANUARY 26, 2001

Significantly, I note that Dr. Levin *misidentified* DAC's vaccination of January 26, 2001, as a DTP vaccination rather than a DTaP vaccination.[22] This *might* allow for an inference that he intended to rest his opinion at least in part on that January 26 vaccination in addition to the two prior DTP vaccinations. The distinction is significant, because DAC's vaccination of January 26, 2001, was administered in the United States.[23]

Dr. Levin, however, explicitly contrasted the significance of DTP and DTaP vaccines, indicating that "DTaP is now recommended because the rates of all reactions following the DTaP vaccine are lower than with DTP." (Levin Report, p. 4.) He also stressed that DTP is no longer recommended in the United States. (*Id.*) This suggests that, notwithstanding the fact that Dr. Levin's opinion erroneously identified DAC's DTaP vaccination of January 26, 2001, as a DTP vaccination, his decision to specify DTP, and only DTP, in his causation opinion, was deliberate. At no point did Dr. Levin actually opine that a *DTaP* vaccination, such as the one DAC actually received on January 26, 2001, could have caused DAC's condition, despite also acknowledging that DAC did subsequently receive a DTaP vaccination in *December* of 2001.[24]

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[22] In his medical summary, Dr. Levin indicates that DAC received DTP vaccinations on September 26, 2000, November 23, 2000, and January 26, 2001. (Levin Report, p. 2.) He also indicates that DAC was later given a DTaP vaccination on December 3, 2001. (*Id.*) DAC's September and November DTP vaccinations are confirmed in the records of Dr. Ricardo Gonzales. (Ex. 13, pp. 1-3.) The third DTP dose identified by Dr. Levin, however, does not appear in Dr. Gonzales's records. Rather, it appears on a Yellow Card Vaccination Record subsequently created by Dr. Hope Yerro. (Ex. 14.) DAC's early vaccination entries were apparently hand-copied into that record, which indicates that DAC received a DTP dose on January 26, 2001. (*Id.*) The same entry was copied over to DAC's subsequent records with Kaiser Permanente. (Ex. 27, pp. 1, 3.) None of these copied records specifically identifies the source of this information. However, a chart note from Dr. Teresita Tan indicates that DAC was given a "Dtap" vaccination, not a DTP vaccination, in Dr. Tan's office on January 26, 2001. (Ex. 15, p. 2.). This is also confirmed in Dr. Tan's original immunization record. (Ex. 22.) Therefore, I accept Dr. Tan's original record, rather than the subsequent, copied notations of DAC's vaccine record, as accurate. Thus, based on the medical records, I find that DAC was administered a DTaP vaccination, and not a DTP vaccination, on January 26, 2001.

[23] As noted in footnote 22 above, Dr. Gonzales's records confirm that DAC received two doses of DTP while under his care. Dr. Gonzales also confirmed that he cared for DAC in the Philippines (Ex. 13, p. 3). However, Dr. Teresita Tan, who administered DAC's DTaP vaccine in her office on January 26, 2001, practices in Los Angeles, California. (Ex. 15, p. 6.)

[24] To the extent that Dr. Levin indicated that his opinion was based in part on the temporal relationship between DAC's DTP vaccines and the onset of his autism symptoms, he did *not* specify which vaccine or vaccines he was referring to, nor did he substantiate his claim that the timing is consistent with the medical literature as he claimed. Indeed, he did not even identify the expected time frame he was attempting to reference. Thus, this does not in itself indicate whether Dr. Levin intended to include the vaccination of January 26, 2001, in his opinion or not.

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DR. LEVIN'S EXPERT REPORT IS FACIALLY INADEQUATE

Next, assuming that the vaccinations that DAC received in the Philippines *were* covered by the Program, I will now turn to the substance of Dr. Levin's report. Even assuming, in addition, that Dr. Levin intended to attribute DAC's injury to *both* his two DTP vaccinations of late 2000 *and* his DTP vaccination of January 26, 2001, Dr. Levin's report *still* suffers significant and numerous flaws. In short, it was wholly unpersuasive regarding every element necessary to proving causation-in-fact in this Program.

First, Dr. Levin's opinion regarding *general causation* (*i.e.,* the capacity of the vaccine *generally* to cause the type of injury DAC experienced) is incredibly cursory, and largely, if not entirely, unsupported speculation. His opinion that a causal relationship exists between DTP vaccinations and autism is limited to an alleged, but unexplained, temporal relationship between vaccination and onset *in this case*; an unspecified and unsubstantiated claim that thousands of autism cases have been related to DTP vaccinations; and an allegedly unexplained increase in autism nationwide. (Levin Report, p. 3.) He did not actually offer any *scientific support* for the notion that the DTP vaccine can cause autism, in this or in any case. To the extent that Dr. Levin posited a connection between vaccine-induced encephalitis or encephalopathy and later autism, that alleged link was also completely unexplained and unsubstantiated. Indeed, Dr. Wiznitzer was correct to note that Dr. Levin "offers no causal theory whatsoever." (Ex. A, p. 6.)

Although Dr. Levin did provide a limited bibliography, he did not provide the underlying literature, nor did he link any of the cited work to his specific statements. And in any event, the cited articles themselves do not support Dr. Levin's contentions.[25] Moreover, notwithstanding that he opined a "greater than 50% chance" of a causal relationship, Dr. Levin acknowledged that the entire idea that DTP vaccines *can* cause autism, and the possible causal mechanism by which it could happen, are both the "subject of a debate," leaving Dr. Levin's opinion equivocal in addition to being unsupported. (Levin Report, p. 3.)

Critically, support for the additional contention that the *DTaP* vaccination can cause autism, a contention that Dr. Levin offered implicitly at best, is even more limited. Indeed, Dr. Levin actually stressed that the DTaP vaccine is much *safer* than the DTP vaccine. (*Id.*) His one-sentence "discussion" of DTaP consists solely of an unsubstantiated allegation of unspecified prior instances where compensation allegedly was awarded in this Program for cases where the DTaP vaccine has led to encephalopathy.[26] Yet, even accepting that premise at face

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[25] For example, Dr. Wiznitzer noted that at least one of Dr. Levin's citations was to an article regarding the measles virus. (Ex. A, p. 6.) Yet Dr. Levin specifically excluded the MMR vaccine, let alone the measles virus, from his opinion. (Levin Report, p. 4.)

[26] For both DTP and DTaP vaccinations, "encephalopathy or encephalitis" constitutes a Table Injury if it occurs within 72 hours of vaccination. (42 C.F.R. § 100.3(a).) Critically, however, Table Injuries carry a presumption of causation only when the injury fits the statutory definition and when onset falls within the prescribed period. In the instant case, however, there is no interpretation of the record that could establish DAC's injury as a Table Injury encephalopathy or encephalitis. Dr. Levin also did not adequately address the *timing* of the encephalopathy he claims to have occurred (he failed to specify its onset and also failed to identify a specific vaccine as causal). To the

value, Dr. Levin did not even attempt to address, let alone persuasively address, the supposed further link between encephalopathy and autism. Instead, he stated only that some children have "moderate reactions" to vaccination, such as fever, crying, and seizure. He did not, however, offer any explanation for how such a reaction could ultimately lead to *autism*.[27] (Levin Report, p. 4.)

Moreover, Dr. Levin's discussion of *specific causation* (*i.e.,* the idea that DAC's vaccines actually *did cause his own injury*) is equally unpersuasive. In fact, Dr. Levin's causal opinion is predicated entirely on the alleged presence of a temporal relationship between vaccination and injury. This alone leaves the opinion inadequate. (*See, e.g., LaLonde v. HHS*, 746 F.3d 1334, 1341 (Fed. Cir. 2014)(holding that "the basis for Ms. LaLonde's petition reduces to a temporal relationship between the administration of the DTaP vaccine and M.L.'s focal brain injuries. As we have stated before, a temporal correlation alone is not enough to demonstrate causation"); *see also Althen*, 418 F.3d at 1278 ("Although probative, neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation").) Yet, even Dr. Levin's opinion regarding that alleged temporal relationship is itself deeply flawed.

As noted above, Dr. Levin's very limited discussion of DAC's medical history was mistaken on the critical point of identifying the type of vaccinations that DAC actually received. Mistaking DAC's vaccination of January 26, 2001, as a DTP rather than a DTaP vaccination is particularly glaring in light of Dr. Levin's clear distinction regarding the relative safety of those two different types of vaccinations, and his contention that the *DTP vaccinations* were causal. The mistake also highlights the report's overall vagueness.[28]

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extent that Dr. Levin spoke of any "first symptom," it was in regard to DAC's *autism*, not any supposed encephalopathy or encephalitis, and onset was pegged at around August 3, 2001. (Levin Report, p. 2.) Petitioners also alleged that the first symptom of DAC's injury arose around the time of his first birthday on July 17, 2001, roughly 6 months following his then-most-recent DTaP vaccination. (ECF No. 35.) Although petitioners alleged that DAC experienced a seizure on April 3, 2001 (Ex. 21), this too was months after any of DAC's prior DTP or DTaP vaccinations and, in any event, the existence of that alleged seizure is *not* supported by the medical records. (*See* Section IV(B) above.) Therefore, absent a Table presumption, it was incumbent upon Dr. Levin to establish that DTaP vaccines can, in fact, cause the type of injury DAC allegedly sustained. In and of itself, and particularly in light of the potential for a causal presumption under the Vaccine Injury Table, the fact that prior claims have been paid does not establish causation *in this case*.

[27] As discussed in footnote 5, above, in *Wright v. HHS*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015), Special Master Vowell concluded that a child, later diagnosed with ASD, suffered a "*Table Injury* encephalopathy" after a vaccination. Special Master Vowell stressed, however, that she was *not* making a judicial determination that the child's autism was *vaccine-caused*. 2015 WL 6665660 at * 30.

[28] The mistake is understandable to *some* degree. As noted in footnote 22 above, there are some records that suggest that the vaccination of January 26, 2001, was a *DTP* vaccination. Indeed, I note that Dr. Wiznitzer made the same mistake. (*See* Ex. A, p. 1.) Nonetheless, the distinction was merely incidental in Dr. Wiznitzer's report, whereas it was central to Dr. Levin's opinion. Had Dr. Levin's report included an appropriate level of specificity, the error likely would have presented itself to him. And even if not, at least Dr. Levin's intention would have been clear. As it stands, however, Dr. Levin's report does not even adequately identify *which vaccines* he considers to be causal.

Dr. Levin reported that DAC received a series of three DTP vaccines (one of which he erroneously identified), and then opined generally that causation can be inferred by the temporal relationship between the onset of autism and the "administrations of DTP vaccine." (Levin Report, p. 3.) That is, though relying entirely on a temporal connection, Dr. Levin failed to even distinguish among the three vaccines (one of which wasn't even DTP) despite the fact that they were administered months apart. Moreover, although he contended that the claimed temporal relationship is consistent with the relevant medical literature, he completely failed to cite any supporting literature, or even remark on what time frame this unspecified literature establishes. And finally, despite seeming to imply that what DAC actually experienced was a "brain inflammation/encephalopathy," which in turn later led to autism (*id.* at 3-4), Dr. Levin discussed only the onset of DAC's *autism,* and did *not* specifically address the timing of any symptom that could be an indication of brain inflammation, encephalopathy, or encephalitis.

Confusingly, to the extent that Dr. Levin opined that "DTP appears to have caused fever, seizures and encephalitis in this case" (Levin Report, p. 4), his summary of DAC's medical history actually seems to link the onset of those alleged symptoms to DAC's Hib vaccination of March 30, 2001, and not to any of his DTP or DTaP vaccinations (Levin Report, p. 2).[29] Thus, it is not even clear how or why Dr. Levin posits a temporal relationship between the DTP vaccinations and DAC's ASD.

For these reasons, Dr. Levin's report is actually quite incoherent. In fact, despite the fact that Dr. Levin clearly stated that he believes DTP vaccinations to be causal, by allegedly causing an encephalopathy/encephalitis that in turn caused DAC's autism, I am unable to detect from his report what Dr. Levin actually believes the time of onset of the alleged encephalopathy to be, let alone determine whether such a time frame conforms to any relevant medical literature.

Moreover, regardless of which vaccine is placed at issue, if Dr. Levin is relying upon an alleged seizure by DAC, the existence of such a seizure occurring at any time soon after his DPT or DTaP vaccinations is *not* supported by the medical records. As addressed above in Section IV(B) of this Decision, there is no mention in the medical records of the seizures that Mrs. Canuto alleged. (Ex. 16, p 1.)

Thus, even looking to the substance of Dr. Levin's report, it still fails to offer any substantial support to the proposition that DAC's ASD was caused by any vaccine at all, let alone being caused by a Program-covered vaccine, such as his DTaP vaccination of January 2001.

[29] Despite this, Dr. Levin apparently opted not to opine that DAC's Hib vaccine – a Program-covered vaccine – was the cause of DAC's injury. (Nor is there any persuasive evidence in the record that DAC's Hib vaccine injured him in any way.)

XI

RESPONDENT'S EXPERT WAS FAR MORE QUALIFIED, AND FULLY REBUTTED DR. LEVIN'S REPORT

For all the reasons above, I have concluded that Petitioners have *failed* to present even a *prima facie* case that any of DAC's vaccinations played *any* role in causing or aggravating his autism. Thus, the burden of proof never shifted to respondent. Nonetheless I further note that Respondent's expert, Dr. Wiznitizer, was far more persuasive than Dr. Levin. Dr. Wiznitzer's opinion in this case fully rebutted Dr. Levin's opinion, which as described above, was very weak in itself. Dr. Witzniter's opinion carried greater weight than Dr. Levin's both because he is better qualified to offer an opinion regarding DAC's neurologic status, including his autism diagnosis, and because his report is more detailed, more coherent, and better supported by the facts and the literature.

Whereas Dr. Levin is a specialist in oncology and hematology (Levin Report, p. 1), two fields unrelated to the instant case, Dr. Wiznitzer is a pediatric neurologist with extensive experience diagnosing autism spectrum disorders, including nearly two decades as director of the Rainbow Autism Center (Ex. B, pp. 1-3). Dr. Levin's experience with autism, in contrast, is limited to three years of special education advocacy during which he claims to have learned much about pervasive developmental disorder (PDD). (Levin Report, p. 1.) Moreover, Dr. Wiznitzer's body of peer-reviewed articles includes papers on subjects related to autism as well as encephalitis and encephalopathy. (Ex. B, pp. 13-19.) Dr. Levin's published works, on the other hand, all pertain to subjects completely unrelated to any of the issues presented by the instant case. (Levin CV, pp. 5-10.) Dr. Wiznitzer's opinion therefore carries greater weight. He is far better qualified to speak, not only to the course and onset of DAC's autism, but also to the question of whether DAC experienced an encephalitis or encephalopathy. Moreover, Dr. Wiznitzer further buttressed his opinion with supporting medical literature.[30]

In any event, Dr. Wizniter's summary of DAC's medical history is much more detailed, and his opinion that the onset of DAC's autism was unrelated to his vaccinations tracks that history much more closely than does Dr. Levin's opinion. Specifically, Dr. Wiznitzer concluded that DAC "has a developmental history with no reported regression of skills. Rather, he displayed a slow acquisition of skills with a gradual appearance of social differences." (Ex. A, pp. 5-6.) Dr. Wiznitzer cited multiple instances in the medical records where DAC's speech delay was noted, not as a regression, but as a failure to obtain significant language development in the first instance, with concerns first being noted at around two years of age. Citing medical literature directly on point, Dr. Wiznitzer concluded that this was a typical developmental trajectory for children with ASD.[31] (Ex. A, p. 6.)

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[30] Although Dr. Levin did provide a brief bibliography, he failed to provide any of the supporting literature and also failed to offer any citations to that literature to support his specific statements. Dr. Wiznitzer, on the other hand, both provided the supporting literature, and directly cited to it to support his assertions.

[31] Specifically, Dr. Wiznitzer cited and submitted the following: Johnson, et al., *Identification and evalulation of children with autism spectrum disorders*, Pediatrics 2007; 120: 1183-1215, and Ozonoff, et al., *The onset of autism: patterns of symptom emergence in the first years of life*, Autism Res. 2008; 1:320-328.

Dr. Wiznitzer also noted the absence of any indication in the contemporaneous medical records that DAC ever experienced an encephalopathy or encephalitis. (Ex. A, p. 6.) Specifically, he correctly observed that there is no contemporaneous medical record reporting any seizure activity (*see* Section IV(B) above), and no subsequent course or treatment consistent with such a concern. (*Id.*) He also noted that, in fact, DAC's medical records from August 3, 2001, and December 3, 2001, specifically document parental reports of the absence of any prior vaccine reactions.[32] (*Id.*, p. 6; *see also* Ex. 17, p. 1 and Ex. 20, p. 1.)

For all these reasons, I find that Respondent's expert submission was much more persuasive than Petitioners' submission. Dr. Wiznitzer fully rebutted Dr. Levin's opinion, providing an explanation of DAC's condition that better accounts for DAC's complete medical history.[33]

XII

PETITIONERS HAVE FAILED THE ALTHEN TEST

As noted above, in its ruling in *Althen*, the U.S. Court of Appeals for the Federal Circuit discussed the "causation-in-fact" issue in Vaccine Act cases. The court stated as follows:

> Concisely stated, Althen's burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between the vaccination and injury. If Althen satisfies this burden, she is "entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine."

Althen, 418 F.3d 1274, 1278 (Fed. Cir. 2005)(citations omitted). In the pages above, of course, I have already set forth in detail my analysis in rejecting Petitioners' "causation-in-fact" theory in this case. In this part of my Decision, then, I will briefly explain how that analysis fits specifically within the three parts of the *Althen* test, enumerated in the first sentence of the

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[32] Subsequently, on October 19, 2004, Mrs. Canuto declined vaccinations, because she believed that they made DAC sick. (Ex. 49, p. 2.)

[33] Although Dr. Wiznitzer opined that DAC's condition is explained as autism, which is in essence idiopathic, I stress that the burden of proof did *not* shift to respondent to prove an alternate cause. Rather, I find Dr. Wiznitzer's opinion to be an effective challenge to Dr. Levin's opinion of vaccine causation. That is, I am considering respondent's evidence relative to Petitioners' case-in-chief. (*See, e.g., deBazan v. HHS*, 539 F.3d 1347, 1353-54 (Fed. Cir. 2008)("The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case in-chief . . . Here, the government's evidence did not concern any factors unrelated to the vaccine. Rather, Dr. Sriram's testimony bore directly on whether the medical evidence supported concluding that the *vaccine* could be the cause-in-fact, which is clearly part of the petitioner's case-in-chief.") (emphasis original).)

Althen excerpt set forth above. The short answer is that I find that Petitioners' theory in this case clearly does not satisfy the *Althen* test.

A. Relationship between Althen Prongs 1 and 2

One interpretive issue with the *Althen* test concerns the relationship between the first two elements of that test. The first two prongs of the *Althen* test, as noted above, are that the petitioners must provide "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Initially, it is not absolutely clear how the two prongs differ from each other. That is, on their faces, each of the two prongs seems to require a demonstration of a "causal" connection between the "vaccination" and "the injury." However, a number of Program opinions have concluded that these first two elements reflect the analytical distinction that has been described as the "can cause" vs. "did cause" distinction. That is, in many Program opinions issued prior to *Althen* involving "causation-in-fact" issues, special masters or judges stated that a petitioner must demonstrate (1) that the *type* of vaccination in question *can* cause the *type* of injury in question, and also (2) that the *particular* vaccination received by the specific vaccinee *did* cause the vaccinee's *own* injury. *See, e.g., Kuperus v. HHS*, 2003 WL 22912885, at *8 (Fed. Cl. Spec. Mstr. Oct. 23, 2003); *Helms v. HHS*, 2002 WL 31441212, at *18 n. 42 (Fed. Cl. Spec. Mstr. Aug. 8, 2002). Thus, a number of judges and special masters of this court have concluded that Prong 1 of *Althen* is the "can cause" requirement, and Prong 2 of *Althen* is the "did cause" requirement. *See, e.g., Doe 11 v. HHS*, 83 Fed. Cl. 157, 172-73 (2008); *Nussman v. HHS*, 83 Fed. Cl. 111, 117 (2008); *Banks v. HHS*, 2007 WL 2296047, at *24 (Fed. Cl. Spec. Mstr. July 20, 2007); *Zeller v. HHS*, 2008 WL 3845155, at *25 (Fed. Cl. Spec. Mstr. July 30, 2008). And, most importantly, the *Federal Circuit* confirmed that interpretation in *Pafford*, ruling explicitly that the "can it?/did it?" test, used by the special master in that case, was equivalent to the first two prongs of the *Althen* test. *Pafford v. HHS*, 451 F.3d at 1352, 1355-56 (Fed. Cir. 2006). Thus, interpreting the first two prongs of *Althen* as specified in *Pafford*, under Prong 1 of *Althen* a petitioner must demonstrate that the type of vaccination in question can cause the type of condition in question; and under Prong 2 of *Althen* the petitioner must then demonstrate that the particular vaccination did cause the particular condition of the vaccinee in question.

Moreover, there can be no doubt whatsoever that the *Althen* test ultimately requires that, as an overall matter, a petitioner must demonstrate that it is "more probable than not" that the particular vaccine was a substantial contributing factor in causing the particular injury in question. That is clear from the statute itself, which states that the elements of a petitioner's case must be established by a "preponderance of the evidence." § 300aa-13(a)(1)(A). And, whatever is the precise meaning of Prongs 1 and 2 of *Althen,* in this case the overall evidence falls far short of demonstrating that it is "more probable than not" that any of the vaccines that DAC received contributed to the causation of DAC's tragic neurodevelopmental disorder.

B. Petitioners have not established Prong 1 of Althen in this case.

As explained above, under Prong 1 of *Althen* a petitioner must provide a medical theory demonstrating that the *type* of vaccine in question can cause the *type* of condition in question. Here, Petitioners did not even minimally support their theory that the type of injury DAC experienced could have been vaccine-caused. Although Petitioners themselves submitted

extensive writings regarding their theory of causation, I have not found those filings to be persuasive evidence in this case for the reasons described above, leaving only Dr. Levin's opinion. Dr. Levin's opinion, in turn, focused on non-U.S. vaccinations that may not even be covered by this Program. Moreover, he left his assertions completely unsupported. Even assuming that all of the vaccinations to which Dr. Levin points were covered by the Program, and granting Dr. Levin his unsupported assumption regarding the alleged causal relationship between DTP/DTaP vaccinations and encephalopathy/encephalitis, he completely failed to address how those injuries could ultimately manifest as *autism*. Thus, Petitioners' claim fails under *Althen* Prong 1.

C. Petitioners have failed to establish Prong 2 of Althen in this case.

Under Prong 2, the Petitioners need to show that it is "more probable than not" that one of DAC's vaccinations *did* cause DAC's *own* condition. But this they have failed to do, for all of the reasons detailed above. In terms of establishing causation in DAC's case in particular, Dr. Levin relied entirely on an alleged temporal connection between DAC's vaccination and his injury. This alone leaves Dr. Levin's opinion inadequate, because no such temporal association has been demonstrated. Dr. Levin completely failed to substantiate this assertion. He did not explain what he considered the time of onset to be in this case. Nor did he explain more generally what he considered a medically acceptable time frame for the onset of the type of injury at issue. Additionally, to the extent that Dr. Levin believed DAC's autism was actually the result of an encephalitis/encephalopathy evidenced by fever and seizure, his opinion was silent regarding the *onset* of that alleged encephalopathy/encephalitis, speaking only to the onset of DAC's *autism*. Further, his summary of DAC's medical history, confusingly, mentioned a seizure only in connection with DAC's Hib vaccine, which Dr. Levin did *not* opine to be causal. But in any event, I decline to credit the allegation of a seizure even at that time, because it was not corroborated by the medical records. Thus, for all these reasons, Petitioners have failed to establish Prong 2 of *Althen* in this case.[34]

D. Petitioners have failed to establish Prong 3 of Althen in this case.

Since I have explained why Petitioners have failed to satisfy the *first* and *second* prongs of *Althen*, I need not discuss why Petitioners' case also fails to satisfy the *third* prong, under which Petitioners must show a proximate temporal relationship between vaccination and injury. However, I will note again that Dr. Levin utterly failed to establish either the period of onset in DAC's case *specifically,* or the medically accepted time frame for such a condition *generally*.

E. This is <u>not</u> a close case.

As noted above, in *Althen* the Federal Circuit indicated that the Vaccine Act involves a "system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants." 418 F.3d at 1280. Accordingly, I note here that this case ultimately is *not* a

[34] To clarify, Petitioners have failed to show that DAC's autism was either *initially caused* by any of his vaccinations, or was aggravated in any way by his vaccinations.

close case. For all the reasons set forth above, I found that Dr. Levin's theory was *not at all* persuasive, while Respondent's expert was *far* more persuasive.

XIII

CONCLUSION

The record of this case demonstrates plainly that DAC and his family have been through a tragic ordeal, and I have great sympathy for the family. However, I must decide this case not on sentiment, but by analyzing the evidence. Congress designed the Program to compensate only the families of those individuals whose injuries or deaths can be linked causally, either by a Table Injury presumption or by a preponderance of "causation-in-fact" evidence, to a listed vaccine. In this case, the evidence advanced by the Petitioners has fallen far short of demonstrating such a link. Accordingly, I conclude that the Petitioners in this case are *not* entitled to a Program award on DAC's behalf.[35]

George L. Hastings, Jr.
Special Master

[35] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.